

Sub A13

THE

a demand valve having a supply inlet port adapted to be connected to the pressurized source, an outlet port adapted to be connected to the appliance's inlet, a reference chamber and a valve assembly responsive to the reference chamber pressure and a pressure representative of the appliance inlet pressure for connecting and disconnecting the inlet port to and from the outlet port; and

20

1 2. The invention of claim 1 wherein the demand
valve includes an outlet chamber upstream from the outlet
port, the pressure in the outlet chamber being
representative of the pressure in the breathing appliance
5 inlet.

1 3. The invention of claim 1 wherein the valve
assembly includes a first or main valve connected between
the inlet and outlet ports and a main valve controller
responsive to the difference in the pressure in the
reference chamber and the representative appliance inlet
pressure for causing the first valve to open and connect
the inlet port to the outlet port when the representative
appliance inlet pressure falls below the pressure in the
reference chamber and for causing the main valve to close
to disconnect the inlet from the outlet port when the
representative of the breathing appliance inlet pressure
rises to the pressure in the reference chamber.

1 4. The invention of claim 3 wherein the main valve
controller comprises a second valve.

1 5. The invention of claim 4 including a pressurized
nebulizer outlet and a third valve responsive to the
status of the second valve for connecting and
disconnecting the nebulizer outlet to the inlet port when
5 the second valve is closed and opened, respectively.

1 6. The invention of claim 4 wherein the main valve
comprises a diaphragm valve with first and second
actuating chambers disposed on opposite sides of the
diaphragm, the area of the diaphragm exposed to the
5 second chamber being smaller than the area of the
diaphragm exposed to the first chamber whereby the main
valve will remain closed when the pressure in the two
actuating chambers is substantially the same and will
open when the pressure in the first chamber falls below
10 the pressure in the second chamber by a preset amount.

1 7. The invention of claim 6 wherein the third valve
is a diaphragm valve with first and second chambers
disposed on opposite sides of the diaphragm, the first
chamber being in fluid communication with the first
5 chamber of the main valve, the second chamber of the
third valve being in fluid communication with the
nebulizer outlet and with the second chamber of the main
valve through a flow restrictor.

1 8. The invention of claim 6 wherein the second
valve comprises a diaphragm valve with the reference
chamber and a second chamber disposed on opposite sides
of a pressure sensing diaphragm, the second chamber being
5 in fluid communication with the outlet port.

1

9. The invention of claim 8 wherein both chambers of the main diaphragm valve are connected to the inlet port, the connection to the first chamber including a restrictor for restricting the flow rate.

1

10. The invention of claim 9 wherein the second diaphragm valve further includes a normally closed pilot valve connected to the first chamber of the main valve, the pilot valve opening to connect the first chamber of the main valve to the second chamber of the second valve in response to the movement of the sensing diaphragm as a result of the pressure in the second chamber of the second valve falling below the pressure in the reference chamber.

11. The invention of claim 10 wherein the pilot valve includes a spring biased member which maintains the pilot valve normally closed.

1

12. The invention of claim 9 wherein the third valve is a diaphragm valve having first and second actuating chambers disposed on opposite sides of the diaphragm, the first chamber being in fluid communication with the first chamber of the main valve, the second chamber being in fluid communication with the pressurized nebulizer outlet.

5

1 13. The invention of claim 3 wherein said at least
one adjustable pressure regulator includes a line with a
flow restrictor connected between the pressurized source
and the reference chamber and a first adjustable poppet
5 valve connected between said line upstream from the flow
restrictor and atmosphere.

1 14. The invention of claim 4 wherein said at least
one pressure regulator comprise two pressure regulators,
at least one which is manually adjustable and a
inhalation/exhalation selector, the two pressure
5 regulators in conjunction with the selector being
arranged to set the pressure in the reference chamber at
one level during the inhalation phase and at a different
level during the exhalation phase.

1 15. The invention of claim 14 wherein the reference
chamber is connected to the pressurized source through a
restrictor and wherein each pressure regulator includes
a poppet valve, each poppet valve having an inlet and an
5 outlet, the outlets being in fluid communication with the
atmosphere, the inlet of one of the poppet valves being
in constant fluid communication with the reference
chamber upstream from the restrictor, and further
including a fourth valve for placing the inlet of the
10 other poppet valve in fluid communication with the

reference chamber, upstream of the restrictor, in response to the closure of the main valve.

1 16. The invention of claim 15 wherein both pressure regulators are manually adjustable.

1 17. The invention of claim 15 wherein the fourth valve is a diaphragm valve.

1 18. The invention of claim 17 wherein the fourth valve includes first and second chambers disposed on opposite sides of the diaphragm with the first chamber being in fluid communication with the nebulizer outlet and the second chamber being in fluid communication with the reference chamber.

1 19. The invention of claim 14 wherein the other pressure regulator is not manually adjustable by an operator in the field and functions to set the pressure in the reference chamber at a set pressure above the exhalation reference pressure during the inhalation phase.

1 20. The invention of claim 19 wherein each of the pressure regulators includes a poppet valve and the selector comprises a diaphragm valve.

1 21. The invention of claim 2 further including a
nozzle disposed upstream of the outlet port and in an
educting relationship with the outlet chamber so that the
pressure in the outlet chamber varies with the flow rate
5 of gas through the nozzle to compensate for pressure
losses between the outlet port and the breathing
appliance inlet.

1 22. ^{a15} A method of treating a patient suffering from
pulmonary edema or other respiratory ailment comprising:

sub 915
a) securing a breathing appliance to the
patient's airway, the appliance having an
inlet and an inhalation/exhalation valve to
allow breathable gas passing through the inlet
to enter the patient's lungs during the
inhalation phase and allow expired air to exit
to atmosphere during the exhalation phase;

10 b) providing a pressurized source of
breathable gas;

c) providing at least one reference
pressure at a selected value above atmospheric
pressure;

15 d) monitoring the pressure at the
appliance inlet;

Subas
20 Cont.

e) comparing the appliance inlet pressure with the reference pressure;

f) connecting and disconnecting the pressurized source to the mask inlet when the inlet pressure falls below and rises to the reference pressure, respectively; and

g) varying the selected value of the reference pressure during the treatment.

23. The method of claim 22 wherein the reference pressure is varied to accommodate the patient's ability to tolerate higher or lower lung pressures.

24. The method of claim 23 wherein the reference pressure is varied so that the reference pressure is greater during inhalation than during exhalation.

25. In a CPAP apparatus for supplying breathable O₂ from a pressurized source to an individual's breathing appliance, which appliance has a patient valve with an inlet for receiving the O₂ and an inhalation/exhalation valve for routing the O₂ to the individual's lungs and the exhaled air to the atmosphere, the apparatus comprising:

a demand valve having a supply inlet port adapted to be connected to the pressurized source, an outlet port adapted to be connected

to the appliance's inlet, a reference chamber
and a valve assembly responsive to the
reference chamber/appliance inlet pressure
differential for connecting and disconnecting
the demand valve inlet port to and from the
demand valve outlet port; and

at least one back pressure regulator
connected to the pressurized source and the
reference chamber for setting the pressure in
the reference chamber at a selected level
above atmospheric pressure.

26. The invention of claim 25 wherein the valve
assembly includes a first or main valve connected between
the inlet and outlet ports and a main valve controller
responsive to the difference in the pressure in the
reference chamber and the appliance inlet pressure for
causing the first valve to open and connect the inlet
port to the outlet port when the pressure in the
appliance inlet falls below the pressure in the reference
chamber and for causing the main valve to close to
disconnect the inlet from the outlet port when the
appliance inlet pressure rises to the pressure in the
reference chamber.

1000445001

1 27. The invention of claim 26 wherein the main valve controller comprises a second valve.

1 28. The invention of claim 27 including a pressurized nebulizer outlet and a third valve responsive to the status of the second valve for connecting and disconnecting the nebulizer outlet to the inlet port when
5 the second valve is closed and opened, respectively.

1 29. The invention of claim 27 wherein said at least one adjustable pressure regulator includes a line with a flow restrictor connected between the pressurized source and the reference chamber and a first adjustable poppet valve connected between said line upstream from the flow restrictor and atmosphere.

5 30. The invention of claim 29 wherein said at least one pressure regulator comprise two pressure regulators, at least one which is manually adjustable and a inhalation/exhalation selector, the two pressure regulators in conjunction with the selector being arranged to set the pressure in the reference chamber at one level during the inhalation phase and at a different level during the exhalation phase.

1 31. A patient inhalation/exhalation valve for directing breathable gas from a pressure regulated source to a patient's lungs and exhausting the patient's expired

air to the atmosphere comprising:

5 a housing having an upper section and an
interior wall, the housing further having an
inlet adapted to be connected to the regulated
source, an exhaust port in fluid with the
atmosphere and an inlet/outlet chamber adapted
10 to be placed in fluid communication with the
patient's lungs;

an inhalation valve disposed between the
inlet and the inlet/outlet chamber;

5 a flexible diaphragm secured at its
periphery to the inner wall of the housing and
suspending a rigid valve member, the diaphragm
and valve member forming a first chamber with
the interior of the upper housing section;

20 the inlet/outlet chamber terminating at
its upper end in a circular valve seat
arranged to engage a lower circular sealing
area of the rigid valve member, the valve
member and the seat forming an exhalation
valve so that when the valve member is
25 positioned above the seat the exhalation valve
is opened connecting the inlet/outlet chamber
to the exhaust port and when the valve member

engages the seat the exhalation valve is closed;

30 the first chamber being in fluid communication with the housing inlet;

the effective area of the diaphragm and valve member supported thereby being about equal to the area of the circular valve seat whereby the exhalation pressure is maintained at a level approximately equal to the pressure in the inlet.

35 32. The invention of claim 31 wherein the housing defines an annular exhalation chamber surrounding the valve seat in fluid communication with the exhaust port.

33. The invention of claim 32 wherein the exhaust port is formed in an exhaust casing rotatably mounted on the housing.

1 34. The invention of claim 33 wherein the diameter d1 of the effective area of the diaphragm and the medium diameter d2 valve member seat is substantially equal.

add 9th